

REMARKS

Reconsideration of the present application in light of the above amendments and the following remarks is respectfully requested. This Response is filed with a Request for Continued Examination in accordance with 37 C.F.R. §1.114. Claims 1, 2, 5, and 7 are pending, and claims 1, 5, and 7 are currently amended. Claim 8 remains withdrawn. Claims 3, 4, 6, and 9-27 are canceled without prejudice to any future filings of one or more continuation and/or divisional application(s). Support for the amendments may be found throughout the specification and claims as originally filed. In particular, support for the amendments to claim 1 may be found, for example, at originally filed claim 4 (the content of which was incorporated into amended claim 1), as well as at lines 28-29, page 18; lines 13-15, page 19; lines 5-9, page 20, of the instant specification. No new matter has been added to the application by way of amendment.

**Claim Objections**

Claim 7 stands objected to for the misspelling of “thermophilus.” Applicants thank the Examiner for noting this oversight and respectfully submit the misspelling has been corrected as requested. Accordingly, Applicants respectfully request this objection be withdrawn.

**Rejection under 35 U.S.C. § 112, Second Paragraph**

Claims 1, 2, 4, 5, 7, 11, and 27 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Action alleges claim 1 is confusing in that it recites method steps of “wherein the bacteria are purified or isolated,” and it is allegedly unclear as to whether the “nutrient” is for the bacteria recited in the claim, or for any bacteria. The Action further alleged there was insufficient antecedent basis for “liquid medium” of claim 11 or “solid medium” of claim 27. Applicants traverse this rejection and submit the presently pending claims distinctly claim the subject matter which Applicants regard as the invention.

As an initial matter, Applicants note that claims 4, 11, and 27 have been canceled, rendering moot the rejection with regard to those claims. In addition, without acquiescing to this rejection, Applicants have amended claim 1 for clarification and in the manner suggested by the Examiner. Accordingly, Applicants submit this rejection has been overcome and respectfully request it be withdrawn.

**Rejection under 35 U.S.C. § 102(b)**

Claim 1 stands rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Gatto et al. (1998 *J. Biol. Chem.* 273: 10578-10585). Specifically, the Action alleges Gatto et al. teach growing bacteria in LB agar with bacterial nutrients and kanamycin antibiotic. Applicants respectfully traverse this rejection and submit the cited reference does not anticipate the presently claimed invention.

It is well established that in order to anticipate a claim, the cited reference must teach each and every element of the claim. *See Verdegaal Bros. v. Union Oil Co. of Calif.*, 814 F.2d 628, 631 (Fed. Cir. 1987). Applicants submit that the cited reference merely disclosed growing bacterial cultures, and does not teach a kit comprising the multiple elements presently claimed. Nonetheless, without acquiescing to this rejection, Applicants have amended claim 1 for clarification. Accordingly, Applicants submit this rejection has been overcome and respectfully request it be withdrawn.

**Rejection under 35 U.S.C. § 103(a), First Rejection**

Claims 1, 2, 4, 5, 7, 11, and 27 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Farmer (U.S. Patent No. 6,645,506). Specifically, the Action alleges Farmer teaches therapeutic compositions comprising *Bacillus coagulans* and fructooligosaccharide, along with an antifungal agent, and one of skill in the art would have been motivated to include Nystatin<sup>TM</sup> as the antifungal agent. Applicants respectfully traverse this rejection and submit the cited reference does not render obvious the presently claimed invention. Applicants note that claims 4, 11, and 27 have been canceled, rendering moot the rejection with regard to those claims.

Applicants submit Farmer teaches topical application of specific bacterial compositions and nowhere teaches or suggests a kit or composition comprising isolated or purified bacteria, a nutrient for the isolated or purified bacteria selected from the group consisting of: spirulina, chlorophyllins, fructooligosaccharides, and methylsulfonylmethane, an antimicrobial agent, and ascorbic acid, according to the presently claimed invention.

Applicants submit that the Action has failed to establish a *prima facie* case of obviousness according to the well-established criteria of: 1) pointing to some suggestion or motivation to modify the reference, 2) establishing that the skilled artisan would have a reasonable expectation of success, and 3) distinctly pointing out where the cited reference teaches or suggests all of the claim elements. *See In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); MPEP § 2142, § 2143-2143.03. Furthermore, "To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." *Ex parte Clapp*, 227 USPQ 972 (Bd. Pat. App. & Inter. 1985); MPEP § 2142, § 2144-2144.09.

Applicants respectfully submit that, while Applicants are able to recognize the statements containing the conclusion of purported obviousness in the Action, those statements have not been presented in a proper line of reasoning based on the teachings of the cited reference. Specifically, the conclusions do not provide basis *in the cited reference* as to why the skilled artisan would render the presently claimed invention obvious. Applicants respectfully submit that if the conclusion is based on the Examiner's own personal knowledge, then Applicants request specific factual statements and an explanation to be provided in an affidavit or declaration, in accordance with 37 CFR § 1.104(d)(2).

Applicants submit that one of ordinary skill in the art would not render obvious the presently claimed kit in light of the teachings of the cited reference and, at most, may render some embodiments "obvious to try." However, merely because a cited reference may render a particular claimed combination "obvious to try," such standard is not a legitimate test of patentability. *See In re Fine*, 837 F.2d 1071, 1075 (Fed. Cir. 1988).

Nonetheless, solely to expedite prosecution and without acquiescing to this rejection, Applicants have amended claim 1 for clarification. Accordingly, Applicants submit this rejection has been overcome and respectfully request it be withdrawn.

**Rejection under 35 U.S.C. § 103(a), Second Rejection**

Claims 1, 2, 5, 11, and 27 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over van Lengerich et al. (U.S. Patent No. 6,190,591). Specifically, the Action alleges van Lengerich et al. teach a controlled-release capsule comprising a pharmaceutical component that may comprise any number of compounds, including probiotic bacteria. Applicants respectfully traverse this rejection and submit the cited reference does not render obvious the presently claimed invention. Applicants note that claims 11 and 27 have been canceled, rendering moot the rejection with regard to those claims.

Applicants submit that the Action has failed to establish a *prima facie* case of obviousness in this rejection according to the basic criteria set forth above. Applicants submit the Action has failed to provide any suggestion or motivation to modify the cited reference, has failed to establish that the skilled artisan would have a reasonable expectation of success, and has failed to distinctly point out where the cited reference teaches or suggests all of the claim elements. *See In re Vaeck*, and corresponding MPEP sections, *supra*. Furthermore, the Action has failed to support the conclusion of obviousness with a line of reasoning *based on the teachings of the cited reference* as to why the skilled artisan would have found the presently claimed invention obvious. *See Ex parte Clapp*, and corresponding MPEP sections, *supra*.

Applicants submit that the cited reference claims methods for encapsulating and plasticizing matrices in a capsule for slow release particles, and merely includes a single generic statement that nutraceuticals, such as probiotics, may be encapsulated according to the recited methods. Applicants submit that not only is the cited reference nonanalogous art to the presently claimed invention, but that evaluation of an invention under 35 U.S.C. §103 precludes the use of hindsight reconstruction, and instead requires assessment of an invention “as a whole.” *See Ruiz v. A.B. Chance Co.*, 357 F.3d 1270, 1275 (Fed. Cir. 2004). Such assessment requires a showing that one of ordinary skill in the art at the time of the invention, confronted by the same problems

as the inventor and with no knowledge of the claimed invention, would select the various elements from the prior art and combine them in the claimed manner. *Id. See also In re Rouffet*, 149 F.3d 1350, 1358, 47 USPQ2d 1453 (Fed. Cir. 1998). Applicants submit one of skill in the art would not render obvious the presently claimed kit in light of the teachings of encapsulating pharmaceutical compositions of the cited reference.

Applicants respectfully submit that, if the conclusion of obviousness is based on personal knowledge of what is known in the art, then Applicants respectfully request an affidavit or declaration be provided that supports the conclusion with specific facts and explanation in accordance with 37 CFR § 1.104(d)(2).

Finally, solely to expedite prosecution and without acquiescing to this rejection, Applicants have amended the claims for clarification. Accordingly, Applicants submit this rejection has been overcome and respectfully request it be withdrawn.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

All of the claims remaining in the application are now believed to be allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

SEED Intellectual Property Law Group PLLC

*for* Melanie K. Katyon Handfield #57,397  
William T. Christiansen, Ph.D.  
Registration No. 44,614

WTC:hh

Enclosure:  
Postcard

701 Fifth Avenue, Suite 6300  
Seattle, Washington 98104-7092  
Phone: (206) 622-4900  
Fax: (206) 682-6031

746007\_1.DOC